Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	MDL No. 19-2875 (RBK)

SPECIAL MASTER ORDER NO. __

THIS MATTER having been brought before the Court by way of the Motion to Seal Pursuant to Local Civil Rule 5.3 (the "Motion to Seal") filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai U.S. Inc., and Solco Healthcare US, LLC (collectively, "the ZHP Parties" or "ZHP") on notice to liaison counsel for Plaintiffs; and the Court having considered the Parties' submissions and proposed sealed information, and the factors contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the standards set forth therein have not been met, the Court makes the following Findings of Fact and Conclusions of Law:

1. Preliminarily, the Court notes that "in cases involving large-scale discovery, the court may construct a broad umbrella protective order upon a threshold showing by the movant of good cause." *In re Avandia Mktg., Sales, and*

Prods. Liab. Litig., 924 F.3d 662, 671 n.5 (3d Cir. 2019) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 n.17 (3d Cir. 1994)). "However, Courts must be vigilant to assure Confidentiality Orders are not overused and are only used for legitimate purposes." *In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Prods. Liab. Litig.*, 512 F. Supp. 3d 546, 550 (D.N.J. 2021). This Court has previously noted that "the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery." *Id.*

2. Thus, when a party challenges a designation under an umbrella protective order, "'the party seeking to maintain the seal must justify the continued sealing of those documents..." *Avandia*, 23 F. 3d at 671 n.5 (quoting *Pansy*, 23 F.3d at 787 n.17). "In *Pansy v. Stroudsburg*, 23 F. 3d 772 (3rd Cir. 1994), the court expounded on the burden to justify confidentiality." *Valsartan*, 512 F. Supp. 3d at 550. There, the Third Circuit set forth seven factors to consider when deciding a motion to seal:

1. whether disclosure will violate any privacy interests;
2. whether the information is being sought for a legitimate purpose or for an improper purpose;
3. whether disclosure of the information will cause a party embarrassment;

> 4. whether confidentiality is being sought over information important to public health and safety;
>
> 5. whether the sharing of information among litigants will promote fairness and efficiency;
>
> 6. whether a party benefitting from the order of confidentiality is a public entity or official; and
>
> 7. whether the case involves issues important to the public.

Avandia, 924 F.3d at 671 (emphasis added) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3 476, 483 (3d Cir. 1995) (citing *Pansy*, 23 F.3d at 787-91)). In *Pansy*, the Third Circuit also held that "where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law." 23 F.3d at 791. Importantly, this standard applies "when [a court] review[s] orders preserving the confidentiality of discovery materials pursuant to Federal Rule of Civil Procedure 26." *Avandia*, 924 F.3d at 670 (citing *Pansy*, 26 F.3d at 783-92).

3. "[T]he more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access." *Id.* (emphasis added) (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)).

> The common law right of access "antedates the Constitution." *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d [339,] 343 [(3d Cir. 1986)]. The right of access "promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court." *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access "diminishes possibilities for injustice, incompetence, perjury, and fraud." *Id.* Moreover, "the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness." *Id.*

Avandia, 924 F.3d at 672. Thus, once a document "has been filed with the court ... or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings," "a presumption of access attaches." *Id.* (emphasis added) (quoting *In re Cendant Corp.*, 260 F.3d at 192).

4. "To overcome that strong presumption, the District Court must articulate 'the compelling, countervailing interests to be protected,' make 'specific findings on the record concerning the effects of disclosure,' and 'provide[ ] an opportunity for interested third parties to be heard.'" *Id.* at 672-73 (quoting *In re Cendant Corp.*, 260 F.3d at 194). "In delineating the injury to be prevented, specificity is essential," so "[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Id.* at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (emphasis added). In sum, "[c]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be

overcome by the secrecy interests of private litigants." *Id.* (emphasis added) (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)).

5. Moreover, although some of the seven *Pansy* factors are relevant to a court's analysis under the common law standard, two are explicitly not considered. *Id.* at 677. First, the Third Circuit has "repeatedly said that concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access." *Id.* (emphasis added) (collecting cases). Second, "a person's motive for inspecting or copying judicial records is irrelevant under the common law right of access." *Id.* at 677.

6. In considering the remaining five factors, the Third Circuit has put its "thumb on the scale in favor of openness—the strong presumption of public access[:]"

> [T]he public's right of access must be the starting point, not just one of multiple factors. The scale is tipped at the outset in favor of access. And the right of access is not a mere formality—it "promotes public confidence in the judicial system"; "diminishes possibilities for injustice, incompetence, perjury, and fraud"; and "provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness." *Littlejohn*, 851 F.2d at 678. These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.

Avandia, 924 F. 3d at 677 (emphasis added). Moreover, "[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm." *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196). On the other hand, "blanket assertions of harm that 'could' come to fruition fall short of the clearly defined and serious injury that [a movant] must articulate to obtain sealing under any standard." *Id.* at 679. As discussed below, ZHP fails that test, and cannot meet it with regard to presumptively public documentation of the facts surrounding its wholesale contamination of a trusted blood pressure drug, a drug that is no longer sold by ZHP in the United States.

7. After the Third Circuit vacated and remanded its original decision to seal the documents in *Avandia*, the trial court applied the correct standard and wrote:

> Justice Brandeis famously declared that "sunlight is the most powerful of all disinfectants." Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents. Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.
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> *In re Avandia Mktg, Sales Practices and Prods. Liab. Litig.*, 484 F. Supp. 3d 249, 268 (E.D. Pa. 2020).

8. In one of its prior confidentiality rulings in this case, the Court noted that it "is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents." *Valsartan*, 2512 F. Supp. 3d at 553.

9. In this motion, ZHP has asked the Court to seal parts of the September 10, 2021 transcript related to the July 27, 2017 email. (ECF 1584-3, ¶ 12-13). Preliminarily, the Court notes that ZHP's motion does not specifically analyze any of its requested redactions in its proposed order or index, and Dr. Li's declaration in support of the motion is similarly vague and inexplicably based on personal knowledge of an email that he could not recall during his deposition. (ECF 1584; 4/20/2021 Min Li Dep. Tr. 90:14-19, 90:23-91:1). ZHP's motion consequently lacks the specificity required to meet its burden. *See Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (stating, "In delineating the injury to be prevented, **specificity is essential**," so **"[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient**" (emphasis added)); *see also* ECF 1269, p. 8. The Court denies ZHP's motion for this reason alone, but continues its analysis in the alternative.

10. Incredibly, ZHP's own proposed order granting this motion, which was filed on ECF unredacted, includes facts that it is asking the Court to redact from the transcript. (*Compare, i.e.*, ECF 1584-3, ¶ 13 (describing the July 27, 2017 email as

"regarding ZHP's efforts to optimize its process for manufacturing irbesartan"), *with* ECF 1573, 10:17, 18:2-3, 19:7-9). Given the current public record, the Court cannot possibly seal this information.

11. Plaintiffs also note that ZHP has not moved to seal Exhibits A and B to this transcript, which contain the parts of the July 27, 2017 email that it would prefer the Court and public to focus on, as even ZHP's own witness, Min Li, admitted. (4/20/2021 Min Li Dep. Tr. 164:16-19, 165:2-9 (stating, [redacted]). This may be, in part, because the patent at issue is publicly available and thus not confidential by definition. *See* https://patents.google.com/patent/CN103613558A/en. Yet, ZHP inexplicably seeks to redact parts of the transcript concerning this publicly available patent. (*See* ECF 1573, 19:20-22, 20:3-4, 20:10-20, 22:22-33). Even if the email is actually just a commentary on this public patent, as ZHP claims, there is still no basis to seal the email or transcript either.

12. Nonetheless, in accordance with Third Circuit precedent, ZHP's proposed order concedes that the common law public right of access applies to this material. (ECF 1584-3, ¶ 17). *See also Avandia*, 924 F.3d at 672. In addition to "the strong presumption" against sealing these judicial records, this Court recognizes the significant public interest in understanding the nitrosamine contamination at

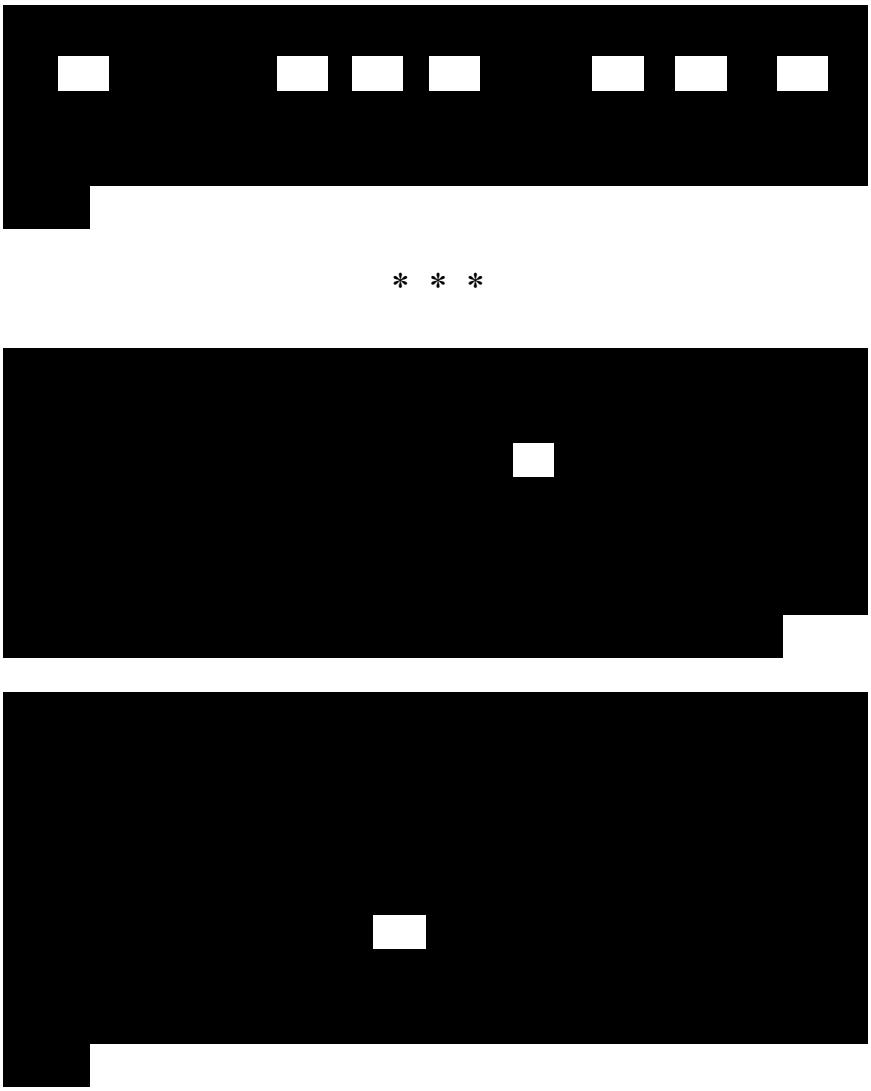
issue in this case as well as in the industry more broadly. *Avandia*, 924 F. 3d 677. ZHP was the first pharmaceutical manufacturer to recall its valsartan due to contamination with carcinogenic nitrosamines, and the issue is not limited to valsartan, losartan, and irbesartan, but ZHP did not disclose the contamination until its customer forced it to do so. FDA, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, https://tinyurl.com/1k9w9jid; FDA, *Information about Nitrosamine Impurities in Medications*, https://tinyurl.com/1tu3nih0. **There is an ongoing public investigation into the cause of this widespread contamination, whether it has occurred with other drugs, and how to prevent it in the future, on top of the FDA's firm determination that the contamination was wrongful and unacceptable, resulting in a complete recall and import ban against ZHP**. In fact, ZHP is still banned from importing its valsartan into the United States because it has not addressed its contamination to the satisfaction of the FDA. FDA, *Import Alert 66-40*, https://tinyurl.com/3jxjmcxc.

13. The July 27, 2017 email states:

[redacted]

* * *

[redacted]



(ZHP 296, which ZHP sent to the Court following the September 10, 2021 hearing). It is public knowledge that ZHP's valsartan, losartan, and irbesartan contained carcinogenic nitrosamines. *See* FDA's Recall Announcement Regarding ZHP's Valsartan, https://tinyurl.com/pubdmu38; FDA's Recall Announcement Regarding ZHP's Losartan, https://tinyurl.com/jbpwxrk; FDA's Recall Announcement Regarding ZHP's Irbesartan, https://tinyurl.com/3eanb2sf. Moreover, it is public knowledge that the valsartan contamination was the result of ZHP quenching the

API to remove sodium azide with sodium nitrite. FDA, *Nitrosamines as Impurities in Drugs; Health Risk Assessment and Mitigation Workshop Day 1*, p. (Mar. 29, 2021) (stating, "**NDMA identified as a process related contaminant in Valsartan NDMA may have been present in batches reaching back to 2012 when the synthesis was changed to a process using dimethylformamide (DMF) as solvent and NaNO2 [(sodium nitrite)] as a quenching agent to destroy azide (sodium azide, used for tetrazole synthesis),"** and **"[a]ll Sartans w[]ith a tetrazole ring system synthesized by this technology expected to be contaminated"**), https://www.fda.gov/media/147331/download; 3/29/2021 Tr. of the FDA's Nitrosamines as Impurities in Drugs; Health Risk Assessment and Mitigation Workshop, 34:11-17 (stating: "[T]he change with the Sartans, the change in the production process to a solvent, dimethylformamide, which of course then can react with nitrite that has been used to quench and destroy the azide that had been used to speed up the tetrazole ring. This then was the cause to form dimethylnitrosamine," which is another name for NDMA), https://www.fda.gov/media/150681/download; FDA, *Nitrosamines as Impurities in Drugs—Health Risk Assessment and Mitigation Public Workshop*, p. 22-23 (Mar. 29-30, 2021) (stating: "For valsartan the issue was the solvent, dimethylformamide, which was heated to high temperatures, promoting formation of dimethylamine. The latter underwent a quenching reaction in the presence of nitrite, which was added for a different purpose, leading to formation of

NDMA. Therefore, this was a side reaction of a side reaction, not direct contamination of the DS or DP"), https://www.fda.gov/media/150932/download; ***see also* ZHP's Patent for Improved Method For Preparing Tetrazole For Valsartan (acknowledging its use of dimethylformamide (DMF) and sodium nitrite quenching in its manufacture of valsartan)**, https://patents.google.com/patent/CN104045602A/en. Thus, the only new information in this email is [redacted] **This is not proprietary information, it is proof of a massive fraud on thousands and thousands of people, payors, and physicians**. **No company would seek out this email and attempt to replicate its defective manufacturing process or** [redacted]**. Rather, it is Exhibit A to a cautionary tale about what happens when financial ambitions (here, to dominate the world market with cheaply manufactured valsartan) eclipse safety considerations.**

14. The Court has denied ZHP's motion to seal numerous other documents concerning ZHP's investigation into and knowledge of the contamination, as well as the violations of current good manufacturing practices (cGMPs) that led to the

contamination.[1] (ECF 1269). ZHP's response (or lack thereof) to the July 27, 2017 email amounts to an unconscionable violation of cGMPs. **ZHP cannot use this Court to continue to hide the information needed for a true understanding of the nitrosamine contamination of its pharmaceuticals.** *See Avandia*, 924 F. 3d at 677 (holding that "we have repeatedly said that **concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access**"); *Valsartan*, 512 F. Supp. 3d at 550 (holding that "**the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused**

[1] **ZHP cites five trial court decisions, all but one of which are unpublished and unopposed, in support of its motion.** (ECF 1584-3, ¶ 21). *Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at *1 (D.N.J. Dec. 6, 2018), *Valeant Pharm. Luxembourg S.à r.l. v. Actavis Labs. UT, Inc.*, No. 2:16-cv-4344, 2018 WL 1469050, at *3 (D.N.J. Mar. 26, 2016), *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 1:14-cv-4727, 2015 WL 4715307, at *1 (D.N.J. Aug. 7, 2015), and *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 WL 27460 (D.N.J. Jan. 3, 2017), were all unopposed motions to seal. Mylan even wrote in support of Boehringer's motion to seal in *Boehringer*, 2015 WL 4715307, at *1. These cases do not support granting ZHP's motion here. In the fifth case—*In re Gabapentin*, 312 F. Supp.2d 653, 669 (D.N.J. 2004)—the court denied an investment research company's motion to unseal summary judgment papers filed in pharmaceutical patent holder's infringement suit against prospective manufacturers of generic version. In that case, the investment research company's entire purpose was to uncover information for the competitive benefit of others. Here, ZHP's motion attempts to prevent the public from understanding how its drug supply became contaminated with carcinogenic nitrosamines and when ZHP knew about that contamination. To the extent it contains any scientific information, the July 27, 2017 concerns manufacturing practices that neither ZHP nor its competitors could use now that their manufacturing defects are widely known and acknowledged by ZHP itself. *Gabapentin* is consequently of no import to this case.

by having to defend claims of wrongdoing the details of which appear in materials produced during discovery"). If there was ever a document that called for the disinfecting rays of the sun, it is this one. *See Avandia*, 484 F. Supp. 3d at 268.

15. Pursuant to the foregoing Findings of Fact and Conclusions of Law:

It is hereby ORDERED this ___ day of _____, 2021 that ZHP's motion to seal the above materials is **DENIED**.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master